

DOCKET NO.: 0010-1106-0

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Re: Serial No.: 09/556,701
Applicant(s): Hitoo NISHINO, et al.
Filing Date: APRIL 24, 2000
For: PHARMACEUTICAL OR FOOD COMPOSITION FOR
TREATMENT OR PREVENTION OF BRAIN EDEMA
GAU: 1615
Examiner: G. KISHORE

SIR:

Attached hereto for filing are the following papers:

1. Response to Restriction Requirement

Our check in the amount of \$ -0- is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. §1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. §1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

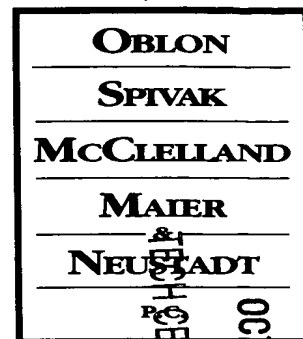
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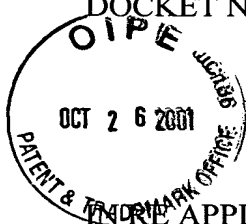


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IN RE APPLICATION OF:

Hitoo NISHINO, et al.

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: GROUP ART UNIT: 1615

SERIAL NO.: 09/556,701

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FILED: APRIL 24, 2000

: EXAMINER: G. KISHORE

FOR: PHARMACEUTICAL OR FOOD COMPOSITION FOR TREATMENT OR
PREVENTION OF BRAIN EDEMA

RESPONSE TO RESTRICTION REQUIREMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Responsive to the Official Action mailed September 26, 2001, the Applicants elect,
with traverse, Group II, Claims 13 and 15 for further prosecution.

REMARKS

The Office has restricted this application as follows under 35 U.S.C. §121:

Group I: Claims 1-12, drawn to a method of treating
brain edema using melatonin; and

Group II: Claims 13 and 15, drawn to pharmaceutical or
food compositions.

Applicants have elected Group II, Claims 13 and 15 with traverse.

The Office has characterized the inventions of Groups II and Groups I as related as
product and process of use. The Office states that the pharmaceutical or food compositions

of Group II can be used for the treatment of melatonin treatable diseases such as neoplastic disease and psychological conditions. However, there is no evidence of record to show that the claimed pharmaceutical or food compositions are useful as the Office has alleged. In addition, the Office has failed to show that the claimed method of treating brain edema using melatonin can be practiced by other anti-edema drugs or steroids as alleged. Accordingly, Applicants respectfully submit that the Restriction Requirement is unsustainable, and it should therefore be withdrawn.

Applicants respectfully traverse on the additional grounds that the Office has not shown that a burden exists in searching the entire application.

Further, MPEP §803 states as follows:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on its merits, even though it includes claims to distinct or independent inventions.

Applicants submit that a search of all claims would not constitute a serious burden on the Office.

Additionally, MPEP §821.04 states:

...if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Applicants respectfully submit that should the elected group be found allowable, the corresponding non-elected process claims 1-12 (Group I) should be rejoined.

For the reasons set forth above, Applicants contend that the Restriction Requirement is improper and should be withdrawn.

Respectfully submitted,
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